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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,215	03/24/2004	Christopher Jude Amies	2002P12618US01	3926

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,215	AMIES ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings were received on 3/26/08. These drawings are accepted.

Claim Objections

Claims 1-31 are objected to as containing a number of informalities. Following is a non-exhaustive list of informalities which are contained within the claims: In claim 1, line 9, “monitoring one or more factors" should read “monitoring of one or more factors, and in line 11 “based on said automatic modification of said initial prescription". In claim 12 and claims 13, line 1, "said automatic monitoring". In claim 17 line 6 to line 7, incomplete thoughts seem to be merged. Specifically, "automatically monitoring one or more factors, exclusive of a position of said area of interest, *that could affect the effectiveness of said automatically delivering said first does of therapeutic radiation* to said area of interest of said patient based on said diagnosis process” appears to contain two separate statements which are not linked. Examiner has implied that the word “therapy” after "said” in line 6 and has examined the claim as such. Additionally, “said automatically calculating” should read “automatic calculation” as it appears to be intended as a noun following the word "said" in line 12. Claim 21, line 3 “automatic calculation of…” Claim 22, line 1 “automatic performance of…” Claims 25-27, line 1 "automatic monitoring..." Finally, in claim 16, line 2 “therapeutic application by” appears to be the intended wording. Appropriate correction is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapatoes et al (US 6,661,870 B2). Kapatoes et al disclose the use of both CT and MRI images in the treatment of an area of interest within a patient and the design of therapy plans before, during, and after rounds of radiation therapy are delivered to the patient (Col 2 Line 18-Col 4 Line 30). Specifically they disclose taking a scout image of the area of interest (Col 5 Line 40-57), creating a plan (Col 5 Line 45-62), validating the initial image once a patient is ready for therapy (Col 5 Line 58-Col 6 Line 30), modifying the treatment plan to account for anatomical and positional changes at this point (Col 6 Line 5-50), delivering a dose of therapy and monitoring the dosage and therapy received during the treatment (Col 7 Line 20-50), updating the plan and performing additional treatment as needed based on anatomical and physiological changes of the diseased state of the patient (Col 7 Line 1-30, Col 3 Line 5-45), including the level of radiation received and therefore the stage of treatment at both the tumor site and the surrounding tissues (Col 6 Line 30-50). These physiological and clinical measurements are performed by imaging in an MRI/CT lab and the updating of the plan can include

modifications between dosing due to unexpected changes in the tumor site thereby inducing an unscheduled break into the therapy session (Col 2 Line 40-47, Col 3 Line 58-Col 4 Line 17). Updated plans are automatically prescribed and are updated further or verified by the operator or treatment planner (Col 3 Line 5-35, Col 3 Line 58-Col 4 Line 17). The plans include dosage levels, target sites, physiological locations and identifications of tissues of interest which are all capable of being updated before, between, or for future therapy sessions (Col 5 Line 34-Col 7 Line 29).

Response to Arguments

Applicant's arguments filed 3/26/08 have been fully considered but they are not persuasive. With regard to the traversal of the number of outstanding objections, Examiner notes and understands that the claims all retain antecedent basis both before and after the suggested changes to the claims; however, the objections as listed were merely to correct grammatical inconsistencies with the English language. None of the claim wording as listed lacks antecedent basis, and as such, these objections are held in abeyance so as to further prosecution on the merits of the instant application. These objections will be retained herein as they are truly minor informalities; however, the current wording is at times difficult to follow.

With respect to the arguments levied against the rejections of the claims, in particular the argument that the monitoring of factors is truly exclusive of a position of an

area of interest within the instant application, and not within the reference of record, Examiner wholeheartedly disagrees with Applicant.

If the currently argued interpretation of “exclusive of a position of said area of interest” were applied against the claims of the instant application, it would create a logical fallacy, as the inherent nature of an "area of interest" implies that an "area", that is some region in space, is being targeted or otherwise focused upon. This "area" would then of course inherently comprise position, and it would require knowledge of that position in order to monitor factors, deliver therapy, or otherwise intentionally perform any medical act on that "area". Claim 2 denotes that the area is a tumor, a tumor which would of course have to be located with respect to its position within the body, and further with respect to the room or space in general. Monitoring one or more factors of that tumor, would require knowledge of the position of the area of interest before monitoring could even take place, so this interpretation of the claim language cannot possibly be that which is desired by Applicant. Furthermore, from Applicant's dependent claims, one can easily see that, stage of disease, stage of treatment, as well as anatomical and physiological variations are desired factors which can be monitored. This monitoring, as stated by Applicant’s claims, can take the form of, imaging, laboratory testing, physiological measurement, or clinical observation.

Turning to the art of record, it is clear that the "area of interest" is imaged and subsequently re-imaged at another point in time. This would fall under the cases of laboratory testing, physiological measurement, imaging, and clinical observation. Additionally, from the images, assessment of the stage of the disease, as is common for

clinicians, as well as anatomical and physiological variations within the area of interest; namely, the tumor is inherently capable of being performed. Furthermore, the steps of delivery verification and dose reconstruction constitute assessment of the "stage of treatment" of an area of interest (please see column 3, line 20-42 for a summary of the steps of this process).

If Applicant's monitoring of an area of interest were truly "exclusive of a position of said area of interest", then the subsequent claims would not logically follow, as it would be impossible to assess an area of interest without knowledge of the position of that area of interest, especially since all the subsequent claims either further define that area of interest, or recite that the factors being monitored are being monitored within that area of interest.

It is well-understood that portions of Kapatoes et al. are focused on the position both of a tumor and of the surrounding tissues in the "area of interest", yet there are monitoring factors which at least comprise those listed within the claims as written, including anatomical and physiological changes, stage of disease, and stage of treatment as recited above. Automatic monitoring can at least comprise laboratory testing, physiological measurement, imaging, and clinical observation within the instant application, as is already discussed above, and through this monitoring a medical practitioner, would have all of the information to inherently be fully capable of assessing the stage of treatment, disease, and physiological changes within the "area of interest".

As discussed above, laboratory testing can comprise imaging, physiological measurement of a patient also can comprise imaging, and clinical observation need

only comprise the use of human hand, or in the instant case, human eye, for assessment. As cited above, column 3 line 20-42 gives a breakdown of an assessment procedure including imaging as a monitoring method as well as dosimetry for the purpose of monitoring the stage of treatment (or the stage of disease as would be inherently observable to the trained eye via images which are produced).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes Fitchard et al (US 6,385,286 B1) which discloses additional relevant embodiments as pertains to the instant case.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action (The inclusion of claim 32). Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/Ruth S. Smith/
Primary Examiner, Art Unit 3737